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March 11, 1986

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Roseland, NJ 07068

RE: Patent Term Extension  
Application for  
U.S. Patent No. 4,309,778  
Issued January 12, 1982

**NOTICE OF FINAL DETERMINATION**

A determination has been made that U.S. Patent No. 4,309,778, issued January 12, 1982, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be ninety (90) days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on August 30, 1985, as follows:

$$\begin{aligned}\text{Period} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (575) + 606 \\ &= 894 \text{ days}\end{aligned}$$

Since the regulatory review period began (August 16, 1980) before the patent issued (January 12, 1982), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the maximum extension. 35 USC 156(c). (From August 16, 1980 to January 12, 1982 is 520 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period:  $1095 - 520 = 575$  days). No determination of a lack of due diligence was made. 35 USC 156(c)(1). The exception of 35 USC 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (April 12, 1985) when added to the period of extension calculated above (894 days) cannot exceed fourteen (14) years. The period of extension is thus limited to April 12, 1999, by operation of 35 USC 156(c)(3). Since the patent term of seventeen (17) years (35 USC 154) would expire on January 12, 1999, the period of extension is the number of days to extend the term of the patent to April 12, 1999 or ninety (90) days. The limitations of 35 USC 156(g)(4) do not operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,309,778 may be made if filed within one (1) month of the date of this notice. In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,309,778, a certificate of extension, under seal, for a period of ninety (90) days. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b).

C. E. Van Horn

Charles E. Van Horn, Director  
Patent Examining Group 120

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs  
Food & Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: New Jersey Meniscal  
Bearing Knee Replacement  
FDA Docket #85E-0296